

### **REMARKS**

Applicant has carefully reviewed and considered the contents of the Office Action mailed March 11, 2003. Reconsideration is respectfully requested in view of the foregoing amendments and the comments set forth below.

By this Amendment, claims 20 and 23 are amended and new claim 26 is added. Accordingly, claims 14-26 are pending in the instant application.

Claims 14-25 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the reasons set forth in paragraph 2 of the Action. Claim 20 is amended so that it is clear that the electrode arrangement is being claimed. In addition, claim 23 is amended to depend from claim 22 to provide sufficient antecedent basis for the “the ring electrodes”. Accordingly, the indefiniteness concerns raised in the March 11, 2003 Office Action have been addressed and it is respectfully submitted that claims 14-26 are fully definite under 35 U.S.C. §112, second paragraph and withdrawal of that rejection is requested.

Claims 14 and 19-24 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,855,592 to McGee et al. (hereinafter referred to as “McGee”) in view of EP 0 601 328 to Ljungström (hereinafter referred to “Ljungström”) as explained in paragraph 4 of the Action. Claims 15-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over McGee in view of U.S. Patent No. 5,834,031 to Cookston et al. (hereinafter referred to as “Cookston”) as described in paragraph 5 of the Action. Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over McGee in view of U.S. Patent No. 4,664,120 to Hess, or in the alternative, under 35 U.S.C.

§103 (a) as obvious over McGee in view of Ljungström and further in view of Hess as described in paragraph 6 of the Action. These rejections are respectfully traversed.

As explained in Section 5 of the Appeal Brief, the invention is directed to an electrode arrangement for endocardial discharge of defibrillation pulses in the atrium or a ventricle of the heart. As shown in Fig. 2b of the instant application, the dash-dotted lines joining electrodes (30 and 32) of the septal branch (14) to unambiguously associated electrodes (30 and 32) of the lateral branch clearly illustrate the layers defined in the atrium by the associated electrode pairs. Page 9, lines 17-27, page 3, line 25 page 4, line 3 and page 5, lines 10-25 of the instant application define what is meant by “unambiguously associated” electrodes. In order to clarify the structure of independent claim 20, Applicant amends the claimed electrode arrangement to positively recite that “each electrically conductive surface portion of the septal branch is unambiguously associated in pairs with an electrically conductive surface portion of the lateral branch” and that “each pair is activated in such a way that the two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation.” As a result of this claimed structure, it is possible for electrodes to be positioned on mutually oppositely disposed side walls of the heart and for the electrodes to be actuated, in bipolar mode so that unambiguously associated electrodes (in pairs) can serve as an anode and a cathode for the discharge of voltage pulses to the myocardium (cardiac tissue) of the atrium. That is, the electrode arrangement according to the invention can assume positions in the heart so that associated electrodes in the septal and lateral branches define layers starting from the transition of the heart into the atrium thereof, thereby subdividing the atrium of the heart in parallel successive relationships, as explained on page 5, line 26 through page 6, line 3 of the instant

specification. As a result of this claimed structure, a defibrillation effect with an extremely low level of stimulation energy and a defibrillation which can be substantially pain-free for the patient can be provided.

Even if the characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area, nowhere does McGee disclose, teach or even suggest that its electrodes are stimulated in pairs wherein each pair is actuated in such a way that two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation, thereby defining a layer in the atrium of the heart. Nowhere does McGee disclose, teach or even suggest electrodes of different branches being stimulated simultaneously in pairs to form a stimulation layer through the heart, as claimed by Applicant. McGee is directed to applying pacing signals from different electrodes at different times (column 4, lines 18-19 of McGee). Nowhere does McGee disclose the inventive operation of the unambiguously associated electrodes in a bipolar mode where the unambiguous association defines a layer in the atrium of the heart and allows stimulation of the same by discharge of voltage pulses.

The secondary reference to Ljungström is applied for its teaching of two branches of a defibrillation system. Nowhere does Ljungström state that each electrode of the septal branch is unambiguously associated in pairs with an electrode of the lateral branch wherein each pair is actuated in such a way that two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation as claimed by Applicant. It is this unambiguous association or pairing of electrodes disposed on different branches that enable the inventive electrode arrangement to achieve a defibrillation effect with an extremely low level of

stimulation energy thereby providing a substantially pain-free defibrillation treatment. Nowhere does McGee or Ljungström recognize the advantage of unambiguously associating in pairs electrodes on different branches. Thus, both McGee and Ljungström, taken alone or in combination fail to teach the claimed invention.

Nowhere does McGee provide a hint that dividing of cardiac tissues may result in a better defibrillation device. It is the dividing of the cardiac tissue, which occurs as a result of the recited electrically conductive surface portions of the septal branch being unambiguously associated in pairs with an electrically conductive surface portion of the lateral branch that enables a defibrillation procedure to employ a lower current level than previously thought possible. Inasmuch as the known prior art, as well as explicit teachings from McGee, teach applying pulsing singles from different electrodes at different times, it is respectfully submitted that one of ordinary skill in the art would not have considered reconstructing the algorithm taught by McGee to that of the claimed invention.

Cookston is directed to an apparatus and method for deflecting a tip of a lead or catheter. Nowhere does Cookston address, let alone disclose, teach or suggest an electrode lead having at least two branches including a septal and a lateral branch where electrically conductive surface portions disposed on a respective branch are unambiguously associated in pairs with an electrically conductive surface portion of the other branch. Moreover, nowhere does Cookston disclose, teach or suggest operating the same in the bipolar mode as claimed by Applicant. Accordingly, Cookston does not provide the teachings missing from the above combination as argued above and can not render the claimed invention obvious.

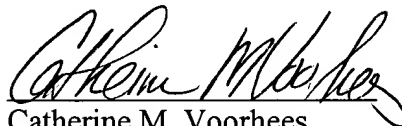
The Action applied Hess for its teaching of a lead configuration that contains two atrium electrode branches 16 and a ventricle branch 15 to provide a multi-functional lead. Nowhere does Hess disclose at least two branches including a septal branch and a lateral branch. Moreover, Hess also fails to disclose, teach or suggest the unambiguously associated in pairs electrically conductive surface portions of any two branches, let alone the claimed septal and lateral branches. Likewise, Hess does not disclose or teach or suggest operating the paired electrically conductive surface portions in a bipolar mode of operation, as claimed by Applicant. Accordingly, Hess does provide the teachings missing from the above combination and cannot render the claimed invention unpatentable.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 14-26 are patentable over the art of record because McGee, Ljungström, Cookston and Hess fail to disclose, teach or even suggest an electrode arrangement where each electrically conductive surface portion of the septal branch is unambiguously associated in pairs with an electrically conductive surface portion of a lateral branch and where each pair is actuated in such a way that the two electrically conductive surface portions are serving as an anode and a cathode in a bipolar mode of operation, as set forth in independent claim 20. Accordingly, Applicant requests the issuance of a Notice of Allowability indicating that claims 14-26 are allowable over the prior art of record.

Should the Examiner believe that a conference would advance the prosecution of this application, the Examiner is requested to telephone the undersigned counsel to arrange such a conference.

Date: June 10, 2003

Respectfully submitted,



Catherine M. Voorhees  
(Registration No. 33,074)

VENABLE

Post Office Box 34385  
Washington, DC 20043-9998  
Telephone: (202) 962-4800  
Direct dial: 202-962-4084  
Telefax : (202) 962-8300

DC2-DOCS1-462209